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To Cement or Not To Cement?

Has the FDA Approved the *Use* of This Device?

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Clinical Practice vs. Investigational Use of Marketed Medical Devices

Medical devices are commercially available for specific indications. On the other hand, good medical practice and patient interest require that physicians have some discretion to use commercially available medical devices according to their best knowledge and judgment. If a physician uses a device for an indication not in the product labeling, however, he or she has the responsibility to be well informed about the device and to base its use on a firm scientific rationale and sound medical evidence. Nevertheless the ***routine use*** of some devices for unapproved uses does not fall within the discretion of the physician, for example, when the unapproved use of the device is known to have an investigational status as does the noncemented use of some porous coated devices.

The ***investigational use*** of a marketed medical device differs from the situation described above. Investigational use suggests the use in the context of a study protocol. When the principal intent of the investigational use of the device is to develop information about its safety or effectiveness, ***an Investigational Device Exemption (IDE) is generally required***. In order to obtain an IDE, the sponsor of the investigation initially determines whether the device is a significant or nonsignificant risk device according to the definition in the IDE regulation, found in Title 21 of the Code of Federal Regulations (CFR), Part 812. If the device is a significant risk device, both Institutional Review Board (IRB) and FDA approval are required before the study may begin. If the device is a nonsignificant risk device, and the IRB concurs, then o
required. FDA considers all
to be significant risk device
instances when an unappro
in an emergency. Guidanc
these circumstances is prov
Register notice entitled "G
Emergency Use of Unappro
(F.R. Vol. 50, No. 204, Tues
ly IRB approval is
orthopaedic implants
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ved device can be used
for the physicians in
ded by a recent *Federal*
idance for the
ed Medical Devices"
ay, Oct. 22, 1985).

***Manufacturers or distribut
may not promote their dev
methods of implantation t
approved labeling.*** For exa
approved and labeled "FO
ONLY," there must be no r
uncemented use is safe or e
representation is not only
law, it is misleading to phy
providers of devices for acc
device usage and perform
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CEMENTED USE
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violation of federal
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Custom Devices

Part 812.3(b)(1) of the Cod
defines a custom device as
one that "Necessarily devia
generally available or from
ance standard or premarke
in order to comply with the
physician or dentist." An i
determine that existing st
ular manufacturer and for
adequate. He then design
one individual patient. The
of Federal Regulations
among other things,
es from devices
an applicable perform-
approval requirement
order of an individual
dividual physician may
k items from a partic-
particular use are not
a device specifically for
physician is, in fact, the specification setter for the device and the resulting product would be a custom device.

In the event this design is adopted for use by other physicians, the device is no longer considered to be a custom device. These points are covered in CFR Parts 812.3(b)(2) and (3), which address the availability of the device, in that the custom device would not be generally available in finished form for purchasing or dispensing.

If the physician or the manufacturer of the unique, one-of-a-kind device decides that this device has commercial value and either labels or advertises it, the custom status is nullified. Either the device is one-of-a-kind and, therefore, a custom device, or it is a commercial product subject to all applicable requirements of the Food, Drug, and Cosmetic Act. Modification of an existing device, or fitting of an existing device to a particular patient, would not make that device into a custom device.

If the physician designs a piece of medical equipment and has this device fabricated to his specifications for use on his patients, it may be a custom device so long as the physician does not make that device generally available. This is covered by CFR Part 812.3(b)(5), "...or is intended to meet the special needs of the physician or dentist in the course of professional practice."

Firms that manufacture custom devices for physicians are subject to the Good Manufacturing Practice and the Registration and Listing regulations. They are ***not*** subject to premarket notification (510(k)).

READEX FICHE

FDA Approval Process for Devices

FDA approves a device for indicated uses through the premarket approval (PMA) process. Devices found equivalent for the indicated use to a device marketed prior to the Medical Device Amendments of 1976 are allowed to be marketed through the premarket notification (510(k)) process. A device not previously marketed and promoted for a specific indication may be studied in human subjects only when authorized by an Investigational Device Exemption (IDE).

Examples of Orthopaedic Devices

Devices approved for use under clinical investigations (IDEs):

- porous coated devices for noncemented fixation
- bone substitutes
- ligaments and tendons
- lasers for arthroscopy
- antibiotic bone cement

Devices approved for specific use after clinical trials (Premarket Approval):

- porous coated hip prosthesis for noncemented fixation: DePuy - AML™ Total Hip System with Porocoat®
- bone growth stimulators:
  Telectronics - Bone Growth Stimulator, Osteostim® 2000;
  EBI - Bi-Osteogen® System 204;
  Zimmer® - Direct Current Bone Growth Stimulator (DCBGS™)
- muscle stimulators for treatment of scoliosis:
  Intermedics - Scolitron®; Medtronic® - Isomod®
- bone cement:
  LD Caulk - Omniplast™; Dentsply - CMW;
  EM Labs - Palacos R®
- knee prosthesis for cemented fixation:
  DePuy - new jersey LCS™ Total Knee

Devices approved for use as being equivalent to devices used prior to the Medical Device Amendments of 1976 (510(k)):

- *me-too* non-porous prostheses
- porous coated prostheses for cemented use
- external fixation devices
- metal-backed acetabular cups for cemented use
- continuous passive motion (CPM) devices
- titanium alloy prostheses
- threaded metal-backed acetabular cups

Examples of devices used for *unapproved* uses:

- porous coated prostheses labeled for use with cement, but implanted without cement
- bone growth stimulators labeled for use on nonunion fractures, but used on fresh fractures, delayed union, or avascular necrosis
- muscle stimulators labeled for single major scoliotic curves, but used on double major curves

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